International Journal of Surgery Protocols 1 (2016) 3–10

Contents lists available at ScienceDirect

International Journal of Surgery Protocols

journal homepage: www.elsevier.com/locate/isjp

The TeaM (*Therapeutic Mammaplasty*) study: Protocol for a prospective multi-centre cohort study to evaluate the practice and outcomes of therapeutic mammaplasty

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ARTICLE INFO

Article history:
Received 10 July 2016
Received in revised form 20 August 2016
Accepted 20 August 2016
Available online 14 September 2016

Keywords:
Therapeutic mammaplasty
Complications
Adjuvant therapy
Breast cancer
Trainee collaboratives
Cohort study

ABSTRACT

Introduction: Wide local excision and adjuvant radiotherapy is the standard of care for early breast cancer. For large tumours, however, mastectomy is frequently recommended as conventional breast-conserving techniques often result in poor cosmetic outcomes. Therapeutic mammaplasty (TM) may extend the boundaries of breast-conserving surgery by combining breast reduction and mastopexy techniques with tumour excision, preserving a natural breast shape and avoiding the need for mastectomy. The prevalence of this operative option among surgeons in the UK and its success rate are unknown. The TeaM study is a multicentre prospective study that aims to investigate the practice and outcomes of TM.

Methods and analysis: Breast centres performing TM will be invited to participate through the research collaborative network and the professional associations. All patients undergoing TM between September 2016 and March 2017 will be included. Demographic, operative, oncological and complication data within 30-days of surgery will be collected. The primary outcome will be unplanned re-operation for complications. Secondary outcomes will include unplanned readmission, re-excision rates and time to adjuvant therapy. Prospective data on 500 patients from 50 centres are anticipated. Exploratory analyses will identify predictors for complications and inform the design of a definitive study.

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http://dx.doi.org/10.1016/j.isjp.2016.08.001

Ethics and dissemination: Research ethics approval is not required for this study. This has been confirmed by the on-line Health Research Authority decision tool. This study will provide novel information regarding the practice and outcomes of TM in the UK. This will inform decision-making for patients and surgeons and inform future research. Dissemination of the study protocol will be via the Mammary Fold Academic and Research Collaborative, the Reconstructive Surgery Trials Network and the professional associations, the Association of Breast Surgery and British Association of Plastic, Reconstructive and Aesthetic Surgeons. Results will be presented at relevant surgical conferences and published in peer-reviewed journals.

1. Introduction

Wide local excision (WLE) and adjuvant radiotherapy is the standard of care early breast cancer [1,2]. For large tumours, however, mastectomy is frequently recommended as conventional techniques often result in unacceptable cosmetic outcomes [3] which can adversely affect patient satisfaction and quality of life [4]. Therapeutic mammaplasty (TM) is a new technique that may extend the boundaries of breast-conserving surgery by combining breast reduction and mastopexy techniques with tumour excision [5,6]. These techniques facilitate adequate resection of larger tumours while preserving a natural breast shape in women with medium to large breasts [7–10]; provide an alternative to mastectomy with or without reconstruction in those with ptotic breasts [6] and may improve outcomes for women with large breasts in whom standard wide local excision followed by radiotherapy may be associated with lymphoedema, fibrosis and chronic pain [11].

Despite the widespread adoption of TM into practice, there is limited high-quality evidence to support the benefits of this approach. The majority of published studies are small, single centre, often retrospective case-series with inconsistent and heterogeneous outcome reporting, the results of which cannot be relied upon. Three recent systematic reviews [11–13] have highlighted the paucity of high-quality outcome data and emphasised the urgent need for well-designed prospective studies to establish the current indications and outcomes of TM. Particular uncertainties relate to the practice of TM in patients with large tumours (>4 cm) beyond the scope of traditional breast conservation; rates and management of margin positivity; predictors of adverse outcomes; the impact of TM on delivery of adjuvant therapy and appropriate assessment of key patient-reported outcomes including quality of life. Data to address these issues and the impact of TM on long-term oncological outcomes such as local recurrence are needed if the procedure is to be offered and bench-marked appropriately. There are, however insufficient data regarding the current indications and outcomes of TM in the UK to allow a definitive study to be designed.

A large prospective study of the current practice of TM is therefore needed to inform the design of a definitive study. Such studies are challenging, but the trainee research collaborative model [14] has emerged as a time and cost-effective means of conducting high-quality large-scale research [15] and audit [16] in surgery. Recent successes with iBRA (implant Breast Reconstruction evAluation Study)

[17–19] and MasDA (Mastectomy Decisions Audit) and the development of a national breast surgical research collaborative [20] have demonstrated that the methodology is both feasible and effective within the context of breast surgery. It is anticipated that this network of highly-motivated breast and plastic surgical trainees and consultants can be utilised to deliver a new study to determine the practice and outcomes of therapeutic mammaplasty in the UK.

2. Methods and analysis

2.1. Aims and objectives

The primary aim of the TeaM (Therapeutic Mammaplasty) Study is to evaluate the current practice and outcomes of therapeutic mammaplasty in the UK.

This will be achieved using the following specific objectives:

i. To determine the number of breast and plastic surgical units offering TM across the UK and the volumes of procedures performed.
ii. To describe the current practice of TM including the indications and techniques used.
iii. To evaluate the 30 day clinical outcomes of TM and explore predictors for adverse outcomes.
iv. To determine the impact of TM on the time to delivery of adjuvant therapy.
v. To establish a network of units performing TM for future research studies.
vi. To inform the feasibility, design and conduct of a future definitive large-scale study including patient-reported and long-term oncological outcomes of TM procedures.

2.2. Hypothesis

Therapeutic mammaplasty is a safe and effective technique for women undergoing breast conserving surgery for invasive or pre-invasive breast cancer with rates of unplanned return to theatre and unplanned readmission to hospital for complications within nationally-defined guidelines for oncoplastic surgical procedures [21].

2.3. Study design

This study will be undertaken employing a national multicentre prospective cohort design using the research collaborative model previously-reported [14] coordinated by the TeaM Study Steering Group.

2.3. Setting

All breast or plastic surgical units in the UK performing TM will be eligible to participate in the study. Units will be invited to participate via the collaborative groups (Mammary Fold Academic and Research Collaborative (MFAC), the Reconstructive Surgery Trials Network (RSTN) and the National research collaborative network) and the professional associations (Association of Breast Surgery (ABS), British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS) and the Association of Surgeons in Training (ASiT)).

2.4. Participants

2.4.1. Inclusion criteria

All female patients over the age of 18 undergoing a therapeutic mammaplasty (TM) procedure. For the purpose of this study, TM will be defined as 'the oncoplastic application of breast reduction or mastopexy techniques including removal of skin to reduce the skin envelope to treat invasive or pre-invasive (ductal carcinoma in situ; DCIS) breast cancer using breast conserving surgery (BCS)' [5,6]. The nipple may or may not be removed pending oncological indication. This will include the following techniques:

- Wise pattern reduction patterns
- Vertical scar mammaplasty techniques
- Benelli mammaplasty techniques
- Tennis racket mammaplasty
- Grisotti flaps
- Horizontal wedge excision

2.4.2. Exclusion criteria

Patient undergoing:

- Standard wide local excision not using any of the techniques listed above
- BCS combined with volume replacement procedures such as latissimus dorsi (LD) mini-flaps, thoracodorsal artery perforator (TDAP) or lateral intercostal artery perforator (LICAP) flaps
- Breast reduction or mastopexy to achieve symmetry or improve the appearance of the breast in a separate procedure from the initial tumour resection
- Mastectomy with or without immediate reconstruction
- Surgery for indications other than invasive or pre-invasive disease

2.5. Outcome measures

The primary outcome will be unplanned re-operation for complications within 30 days of the TM procedure. This is based on the ABS and BAPRAS Oncoplastic Surgery: Guidelines for Best Practice [21] quality criteria (QC16) which states that less than 5% of patients should return to theatre for local complication including wound infection, wound problems requiring debridement or haematoma requiring evacuation [21]. Secondary outcomes will include unplanned re-admission to hospital following discharge home; re-excision of margins, and time to delivery of adjuvant therapy (Table 1). The National Institute for Health and Care Excellence recommends that adjuvant therapy is delivered "as soon as clinically possible within 31 days of completion of surgery" [22].

2.6. Data collection

It is expected that participating centres will recruit consecutive patients into the study. The completeness of case ascertainment will be determined by independent validation of procedure numbers and data collection in selected sites. Any disparity will be explored with the unit concerned and any unit determined to have recruited patients selectively will be excluded from the analysis (see QA section).

All women undergoing TM as previously defined will be identified prospectively from clinics, multidisciplinary team (MDT) meetings and theatre lists.

Simple demographic, co-morbidity, pre-operative planning, operative and oncology data will be collected for all patients. Decisions regarding adjuvant treatment recommendations will be identified from the post-operative MDT meeting.

Table 1
Secondary outcome measures.

Outcome measure	Definition
Unplanned re-operation for local complications	Any re-operation in the 30 days of the initial operation for complications of the TM procedure Any planned return to theatre for oncological reasons such as axillary clearance or further excision of margins as decided at the multidisciplinary team (MDT) meeting or following review of surgical pathology will NOT be included in this category
Re-admission to hospital	Any re-admission to hospital following discharge home after TM directly related to the procedure with either local or systemic complications within 30 days of surgery
Re-excision of margins/completion mastectomy	Any return to theatre for removal of additional tissue in a second operation due to one or more involved/positive margins as recommended by the local multi-disciplinary team. This will include re-excision of margins or completion mastectomy as determined by local MDT decision or elected by patient choice Involved margins will be defined as invasive tumour or ductal carcinoma in situ at or close to the resection margin requiring further surgery (re-excision of margins or completion mastectomy) as defined by local MDT policy (e.g. tumour at ink/<1 mm/<2 mm) Completion mastectomy will be defined as the complete removal of the remaining breast tissue as elected by MDT decision or patient choice.
Time to delivery of adjuvant therapy	Time in days from the TM (or LAST oncological surgery, if applicable) to the first adjuvant treatment (1st dose of chemotherapy or first fraction of radiotherapy)

MDT; multidisciplinary team; TM – Therapeutic mammoplasty.

Data regarding 30 day complications, re-admission and re-operation will be collected prospectively by clinical or case-note review in those not attending for follow-up. Date of commencement of adjuvant therapy will be identified by a review of relevant hospital systems. The required data fields are shown in Table 2 and definitions and categorisation of complications summarised in Table 3.

Data will be recorded in an anonymised format using a unique alphanumeric study identification number on a secure web-based database (REDCap) designed by Vanderbilt University [23] (http://www.projectredcap.org/). Advanced branching logic will be used such that only data fields relevant to the type of surgery will be displayed in later data collection forms. It is anticipated this will reduce the burden of participation for collaborators and optimise the quality of data collected during the study. The data forms and database will be extensively trialled in a three centre pilot prior to national roll-out of the study. This will validate the logic used and ensure that the forms are complete, user friendly, and allow for any errors to be corrected prior to main study initiation.

2.7. Data validation and management

Following data collection, only data sets with >75% data completeness will be included in the analysis [24]. For quality assurance purposes, the consultant principal investigator at selected sites will be asked to identify an independent person to validate a proportion of the submitted data. Overall, approximately 5% of the datasets will be independently validated. The independent assessors will also be asked to examine theatre logbooks, operating diaries and Trust computer systems to check case ascertainment. If concordance between the number of cases submitted on REDcap

Table 2
Data fields for the TeaM study.

Field	Options (definitions)
Section 1 – Demographic data	
Age	Age at diagnosis in years
Height	In metres
Weight	In kilograms
Body mass index	Actual BMI will be collected and categorised as Underweight (<18.5 kg/m^2) Normal weight (18.5–24.9 kg/m^2) Overweight (25–29.9 kg/m^2) Obese (30–34.9 kg/m^2) Severely obese (35–39.9 kg/m^2) Morbid obesity (>40 kg/m^2)
Bra Size	Back and cup size
Sternal notch to nipple distance	In centimetres
Smoking status	Current smoker/Ex-smoker >6 weeks/Non-smoker/Nicotine replacement
Diabetic	Yes/No
Other co-morbidities	Ischaemic heart disease (yes/no); Current steroid therapy (yes/no); Other immunosuppressive therapy (yes/no); Connective tissue disease (yes/no); Other co-morbidity (yes/no) with details
Section 2 – Prior and neoadjuvant treatments	
Previous radiotherapy to ipsilateral breast	Yes/No
Neoadjuvant chemotherapy	Yes/No
Neoadjuvant radiotherapy	Yes/No
Neoadjuvant endocrine therapy	Yes/No
Previous surgery to ipsilateral breast	Wide local excision (yes/no, if yes, date MM/YY); Breast reduction (yes/no, if yes, date MM/YY); Breast augmentation (yes/no, if yes, date MM/YY); Other (yes/no, if yes, date MM/YY)
Section 3 – Pre-operative planning data	
Initial presentation	Screening/Symptomatic
Breast affected	Right/Left/Bilateral
For each affected breast	
Predominant location of tumour by quadrant	Upper outer/Upper inner/Lower inner/Lower outer/Central
Type of lesion	Ductal carcinoma in situ only/Invasive ductal cancer/Invasive lobular cancer/Other
Grade	Cancer: 1/2/3 DCIS: Low/Intermediate/High
Maximum size of lesion at diagnosis on pre-operative imaging in 2 dimensions	Size in largest diameter (mm)
Maximum size of lesion on pre-operative imaging AFTER neo-adjuvant therapy (if used) in 2 dimensions	Size in largest diameter (mm)
Focality	Unifocal (one lesion)/Multifocal (two distinct separate lesions)
Contralateral symmetrisation	Planned simultaneous to TM/Planned for later date/Patient declined
Other treatment options offered to the patient (please tick all that apply)	Standard wide local excision Mastectomy alone Mastectomy with immediate implant-based breast reconstruction Mastectomy with immediate autologous breast reconstruction
Indications for therapeutic mammaplasty (please tick all that apply)	To avoid mastectomy To avoid poor cosmetic outcome associated with standard wide local excision To avoid problems associated with radiotherapy in patients with large breasts Large tumour Quality of life benefits Other
Section 4 – Operative data	
Date of therapeutic mammaplasty	Day/month/year
ASA grade	1 – Normal healthy individual 2 – Mild systemic disease that does not limit activities 3 – Severe systemic disease that limits activities but is not incapacitating 4 – Incapacitating systemic disease which is constantly life threatening
Name of consultant surgeon	
Duration of procedure	Knife to skin to dressings on in minutes
Procedure details collected for RIGHT and LEFT breasts separately. Therapeutic mammaplasty dataset	
Procedure performed	None Therapeutic mammaplasty Reduction/mastopexy for symmetrisation Mastectomy alone Mastectomy and implant-based breast reconstruction Mastectomy and autologous breast reconstruction Other (free text)
The following data will be collected for each TM procedure performed	
Grade of primary operating surgeon	Consultant/Associate Specialist/Senior trainee (ST8+ or Oncoplastic Fellow/ST6-7/ST5 or below/Other
Number of TMs performed using this method in total	<5/5–10/10–25/>25
Number of TMs performed using this method unsupervised	<5/5–10/10–25/>25
Pre-operative localisation	Yes/No
If yes – bracketed	Yes/No
Nipple preserved	Yes on a pedicle/Yes as a free nipple graft/No

Table 2 (*continued*)

Field	Options (definitions)
Skin incision used	Peri or circumareolar with skin excision (round block/Benelli/Racquet) Wise-pattern/Inverted T Single vertical scar/LeJour Grisotti – for central cancers removing nipple Melon slice or horizontal wedge excision (±nipple) Other
Pedicle(s) used to preserve the nipple (if nipple preserved)	Superior/Supero-medial/Medial/Inferior/Central mound/Dual pedicle/Other with details
Tumour excision	Wide local excision performed first followed by the reduction/mastopexy Wide local specimen incorporated in reduction specimen; both procedures performed simultaneously
Intraoperative confirmation of excision	None/Specimen X-ray/Intra-operative frozen section/Intra-operative margin technology e.g. iKnife/ Other
Volume of wide local excision	In grams
Total volume of breast tissue excised (wide local excision + all excised breast tissue)	In grams
Method of marking tumour bed	None/Single clip/Clips to all margins
Axillary surgery	None/Sentinel node biopsy/axillary sample/Axillary clearance
Drains used	Yes/No
Reduction/mastopexy dataset (for patients undergoing simultaneous contralateral symmetrisation)	
Grade of primary operating surgeon	Consultant/Associate Specialist/Senior trainee (ST8 + or Oncoplastic Fellow/ST6-7/ST5 or below/Other
Number of reductions/mastopexies performed using this method in total	<5/5–10/10–25/>25
Number of reductions/mastopexies performed using this method unsupervised	<5/5–10/10–25/>25
Skin incision used	Peri or circumareolar with skin excision (round block/Benelli/Racquet) Wise-pattern/Inverted T Single vertical scar/LeJour Grisotti – for central cancers removing nipple Melon slice or horizontal wedge excision (±nipple) Other
Pedicle(s) used to preserve the nipple (if nipple preserved)	Superior/Supero-medial/Medial/Inferior/Central mound/Dual pedicle/Other with details
Total volume of breast tissue excised	In grams
Drains used	Yes/No
Section 5 – Post-operative oncology and MDT outcomes	
Pathology details for RIGHT and LEFT breasts will be collected separately	
Type of lesion	Ductal carcinoma in situ only/Invasive ductal cancer/Invasive lobular cancer/Other
Grade of invasive disease/DCIS	1 – Low grade (DCIS) or well-differentiated (invasive) 2 – Intermediate grade (DCIS) or moderately differentiated (invasive) 3 – High grade (DCIS) or poorly differentiated (invasive)
Focality	Unifocal – one lesion/Multifocal – two distinct separate lesions
Size of invasive tumour	mm (largest if > 1 ipsilateral tumour)
Total size of lesion including DCIS	In pathological specimen (mm)
Fully excised by local criteria?	Yes/No
Lymph node involvement	Number of involved lymph nodes (macro-metastases only)
ER status	Positive/Negative/Not known
HER2 status	Positive/Negative/Not known
If not fully excised	
MDT decision	Re-excision of margins/Mastectomy/Chemotherapy followed by re-excision of margins/ Chemotherapy followed by mastectomy ± reconstruction
Re-excision 1	
Date of surgery	Day/Month/Year
Surgery performed	Re-excision of margins/Completion mastectomy
Specimen weight	In grams
Cancer/DCIS in re-excision specimen	Yes/No If yes, details
Margins clear	Yes/No
If margins not clear, MDT decision	Re-excision of margins/Mastectomy/Chemotherapy followed by re-excision of margins/ Chemotherapy followed by mastectomy ± reconstruction
Re-excision 2	
Date of surgery	Day/Month/Year
Surgery performed	Re-excision of margins/Completion mastectomy
Specimen weight	In grams
Cancer/DCIS in re-excision specimen	Yes/No If yes, details
Margins clear	Yes/No
If margins not clear, MDT decision	Re-excision of margins/Mastectomy/Chemotherapy followed by re-excision of margins/ Chemotherapy followed by mastectomy ± reconstruction
Re-excision 3	
Date of surgery	Day/Month/Year
Surgery performed	Re-excision of margins/Completion mastectomy
Specimen weight	In grams
Cancer/DCIS in re-excision specimen	Yes/No If yes, details
Margins clear	Yes/No

(*continued on next page*)

Table 2 (*continued*)

Field	Options (definitions)
Oncological decisions	
*This section documents the time from **LAST CANCER SURGERY** to **FIRST ADJUVANT TREATMENT** i.e. first dose of chemotherapy or first fraction of radiotherapy. If patient scheduled for chemotherapy and radiotherapy, please just record the date of first dose of chemotherapy*	
Date of last cancer surgery	DD/MM/YY
Total size of lesion (mm) (if re-excisions)	
Chemotherapy recommended by MDT	Yes/No/already given
If yes	
Date of recommendation	Date/Month/Year
Patient accepts chemotherapy	Yes/No
Chemotherapy start date	Date/Month/Year
Radiotherapy recommended by MDT	Yes/No/already given
If yes	
Date of recommendation	Date/Month/Year
Boost to tumour bed	Yes/No
Radiotherapy start date	Date/Month/Year
Section 6 – 30 day complication data	
Please record any complications that occurs within in the first 30 days following surgery	
Post-operative complication experienced	Yes/No
If yes – details of surgical complications experienced (see Table 3 for definitions)	Seroma
	Haematoma
	Infection
	Skin flap necrosis
	Nipple necrosis
	Wound dehiscence
In hospital complications including systemic complications	Yes/No
	If yes, details
Re-admission to hospital	Yes/No
	If yes – date of readmission (day/month/year)
	Reason for re-admission
Return to theatre	Yes/No
	If yes – date of re-operation (day/month/year)
	Reason for return to theatre
Initial length of stay	Day-case/23 h stay/in patient

ASA – American society of Anesthesiology; DCIS – ductal carcinoma in situ; MDT – multidisciplinary team; TM – therapeutic mammaplasty.

and those identified independently is <75%, the Unit's data will be excluded from the analysis. This is consistent with the quality assurance procedure used in other large collaborative audit projects [24].

Data collection will occur in accordance with Caldicott II principles (http://systems.hscic.gov.uk/infogov/caldicott/caldresources). Data for each patient will be anonymised using a unique alphanumeric study identification number. No patient identifiable data will be recorded centrally for the purpose of the audit.

Study data will be collected and managed using REDCap electronic data capture tools hosted at University of Oxford [23]. REDCap (Research Electronic Data Capture) is a secure, web-based application designed to support data capture for research studies, providing (1) an intuitive interface for validated data entry; (2) audit trails for tracking data manipulation and export procedures; (3) automated export procedures for seamless data downloads to common statistical packages; and (4) procedures for importing data from external sources.

2.8. Anticipated recruitment

Data regarding the numbers of TM procedures performed nationally are lacking. A national survey of specialist centres, however, suggests that between 10 and 20 TM procedures per centre per year may be a reasonable estimate of volume per centre [25]. It is anticipated that the majority of the 144 breast units in the UK will offer TM to their patients. Based on experience from the iBRA study [26] and other trainee collaborative projects [20], approximately 40% of units will choose to participate in the study. It is therefore anticipated that between 250 and 500 patients will be recruited to the study from approximately 50 centres over a six month period. No formal power calculation has been performed, but it is anticipated that data from this study will be used to inform the sample size for the definitive study.

2.9. Study timelines

Data collection and analysis will be undertaken using the following time line

- June-August 2016 – Three centre pilot study, refining of data collection forms
- June-August 2016 – Registration of interest from breast and plastic surgical units. Local unit audit approvals obtained. Participating centres will be required to have registered the study and obtained local approvals prior to the main study start date of 1st September 2016
- 1st September 2016–28th February 2017 – Main study patient recruitment; patients undergoing therapeutic mammaplasty with operation dates between 1st September 2016 and 29th February 2017 are eligible for inclusion in the study
- 28th April 2017 – deadline for data submission
- 1st July 2017 – Data validation complete
- 30th August 2017 – Initial data analysis completed

2.10. Statistical analysis

The study report will be prepared according to the STROBE (Strengthening the Reporting of Observational Studies in Epidemiology) reporting guidelines for observational studies [27]. All data analysis will occur centrally by the TeaM study team with support from statisticians and methodologists in the RCS Surgical Trials Centre.

Table 3
Definitions of 30 day complications.

Complication	Definition	Classification
Seroma	A symptomatic collection of fluid in the operated breast	Only seroma requiring aspiration to be recorded
Haematoma	A collection of blood in the operated breast	Minor – managed conservatively Major – requiring surgical evacuation
Infection	A hot, red swollen breast associated with one of the following; a temperature, pus at the wound site, a raised white cell count; a positive wound culture within the first 30 days of surgery.	Minor – requiring oral antibiotics Major 1 – requiring admission for IV antibiotics Major 2 – requiring surgical drainage or debridement (under GA)
Skin necrosis	Any area of skin loss on the operated breast including the T junction	Minor – managed conservatively with dressings Major – requiring surgical debridement (under GA)
Nipple necrosis	Any area of necrosis of the nipple areolar complex	Minor – managed conservatively with dressings Major 1 – requiring surgical debridement Major 2 – complete nipple loss
Wound dehiscence	Separation of the skin edges at the wound site	Minor – managed conservatively Minor – requiring return to theatre for re-suturing

GA – general anaesthetic.

Simple summary statistics will be calculated for each outcome and multivariate regression analysis used to control for predictive variables. Data will be tested for distribution and differences between clinically relevant groups using unpaired t-tests, Mann-Whitney U tests and Chi squared tests as appropriate. Exploratory analyses will be performed to explore predictors for complications and generate hypotheses for future studies. Summary statistics will be calculated for each participating Trust and fed back to individual units to allow comparison with national averages and ranges.

3. Discussion

Therapeutic mammaplasty may improve quality of life for women who would traditionally experience poor cosmetic outcomes following breast conservation or require a mastectomy as the primary surgical treatment for their breast cancer, but quality evidence to support these benefits is currently lacking. Well-designed prospective data are therefore urgently required to establish the value of TM and support the on-going provision of the procedure to women with breast cancer in the UK.

The TeaM study represents the first important step in establishing a definitive evidence-base to support the role of TM as an essential part of the oncoplastic armamentarium. There are currently insufficient data to inform the design of a definitive study of therapeutic mammaplasty in the UK. The TeaM study will generate high-quality prospective multicentre data regarding the practice and outcomes of the technique and key information regarding the timing of contralateral symmetrisation surgery. This will lead to a well-designed large-scale multicentre cohort study integrating important patient-reported, cosmetic and long-term oncological outcomes which will provide much needed evidence to support practice. The TeaM study will establish current indications for surgery, establish safety by benchmarking TM against national quality criteria for oncoplastic breast surgery [21] and allow predictors for adverse outcomes to be explored. This will provide important information to help patients and surgeons make more informed decisions about their surgical options. Furthermore, the TeaM study will define national standards of care and establish best practice leading to novel guidelines to support centres offering the technique. This is an established methodology as data from the National Mastectomy and Breast Reconstruction Audit [28–31] was used to develop the current oncoplastic guidelines [21]. This will improve outcomes for patients through better standardisation of care.

The use of the trainee collaborative model will allow the study to be conducted in a time and cost-effective manner. It will further consolidate the infrastructure established by the iBRA study [19] and facilitate the delivery of the definitive study by establishing a network of units performing TM who are engaged and interested in undertaking further work in this area. A national study will promote increased awareness and understanding of the technique allowing breast and plastic surgical trainees to learn about the indications, techniques and outcomes of TM which may also improve patient care. Finally, this approach will create research capacity through training future breast and plastic surgeons in research methodology leading to more and better research that will ultimately improve outcomes for patients.

4. Ethics and dissemination

The proposed study will not affect clinical care and compares outcomes to published clinical standards. Research ethics approval is not required and this has been confirmed by the Health Research Authority (HRA) on-line decision tool (http://www.hra-decision-tools.org.uk/research/). A study lead will be identified at each participating centre. If the unit lead is a trainee, the named supervising consultant will act as the principal investigator for the unit for registration purposes. The study lead will be required to register the audit and obtain local audit approvals for study participation prior to commencing patient recruitment. A copy of the approval will be also forwarded to the TeaM study team. Patient consent is not required as no patient identifiable data are being recorded and there is no perceived risk to patients.

The protocol will be disseminated via the collaborative network including Mammary Fold Breast Trainees' Group Academic and Research Collaborative (MFAC), the Reconstructive Surgery Trials Network (RSTN), the Association of Surgeons in Training (ASiT) and the National Research Collaborative (NRC) as well as the professional associations the Association of Breast Surgery (ABS) and the British Association of Plastic Reconstructive and Aesthetic Surgeons (BAPRAS). The protocol and data collection sheets will be available on line (www.themammaryfold.com). Individual centres will have access to their own data. Rates of re-operation and readmission following TM will be calculated for each unit and compared with the national average and quality standards defined by the professional association and NICE. Data will be fed back to participating centres at the end of the study. Overall audit results and results from individual centres will be fed back to ABS and BAPRAS.

Collective data will be analysed and the results of the study presented at relevant scientific meetings and published in peer-reviewed journals. The results of the study will be used to determine national standards and inform patients and surgeons considering surgery in the future.

Authors' contributions

EB, BK and SP contributed to conception, design, writing and editing of the protocol and drafted the paper; AT provided statistical and methodological advice regarding study design; TR, KW, CI, DR, CH, MG, AJ, RS, RA, LB, PT, SA, NB, LB and RDM contributed to study design and advised on the protocol and data collection sheets; PF is the patient representative on the study and advised on design and conduct. All authors are members of the TeaM steering group and read and approved the final manuscript.

Ethical approval

This study does not require ethical approval and this has been confirmed using the HRA on line tool. It involves collection of routine patient data and comparison against published quality standards. All participating centres are required to register the study with their clinical audit departments.

Competing interests

The authors have no competing interests to declare.

Funding

This work has been funded by a Research Grant from the Association of Breast Surgery. The study does not have a sponsor.

Guarantor

Shelley Potter.

Research registration UIN

This study is being pragmatically conducted as a clinical audit as per several published collaborative projects. It therefore has not been registered on a research registry.

Appendix A. Supplementary data

Supplementary data associated with this article can be found, in the online version, at http://dx.doi.org/10.1016/j.isjp.2016.08.001.

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